UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,212	09/05/2003	Joel H. Webbe	42397-192272	8492

26694 7590 12/01/2004

VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
LEITH, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/655,212	WEBBE ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-22 and 24 in the reply filed on 8/27/04 is acknowledged. Claim 22 was inadvertently omitted from the original restriction requirement as pointed out by Applicant. Claim 22 should have been placed in the Invention of Group I as correctly contended by Applicant.

Claim 23 is hereby withdrawn from further consideration on the merits as it is directed toward a non-elected invention.

Claims 1-22 and 24 were examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

In the Instant case, Applicant is claiming a nutmeg oil which has particular chemical constituents such as bornyl acetate, beta-citronellol and 1-t-carophyllene. There is nowhere in the Instant specification that teaches what nutmeg oil the claim is refering to, how to make such a composition, or where to purchase such a composition.

Lacking such critical information in the Instant specification, the skilled artisan would have to test all known nutmeg oils in order to ascertain what nutmeg oils actually possess the claimed phytochmicals, thereby creating undue experimentation involving rigorous, timely and expensive laboratory trial and error protocols.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 8, 12,13, 16,17 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Morri I. (JP 362059219 A) in light of International Programme on Chemical Safety Poisons Information Monograph 355 (IPCSPIM) (1997).

Morri I. (JP 362059219 A) disclosed a composition possessing analgesic effects which comprised 10% menthol and 5% nutmeg oil (please see English Abstract). It is well known in the art that *Myristica fragrans* is nutmeg, and therefore, it would flow naturally from the recitation of 'nutmeg oil' that the nutmeg oil is derived from *Myristica fragrans.*

It is noted that the addition of a container, as well as labeling instructions does not materially change the composition of claim 1, and therefore claims 16 and 17 are anticipated.

Where claim 21 states that the nutmeg oil and menthol are effective to relieve pain without additional non-menthol analgesics, is also non-limiting because it does not change the composition, but rather states a characteristic of the composition.

Nutmeg oil is prepared from steam distillation of *Myristica fragrans* as indicated by IPCSPIM (see p. 8 of 23).

It is determined that claim 22, which states "method for treating....administering....a pain relieving formulation comprising nutmeg oil and added menthol in an amount effective to relieve pain, without administering other analgesics is anticipated by Morri I. for the following reason: Although the claim states 'an amount effective to relive pain, without administering other topical analgesics' does not mean

that other analgesics are not present in the composition. This statement simply means that if there were no other analgesics present, that the nutmeg oil and menthol would relieve pain alone, which is rendered an inherent property of the composition.

Finally, wherein claim 8 states 'consists essentially of nutmeg oil and added menthol' is deemed to be anticipated by Morri considering there is no evidence to indicate that the additional ingredients in Morri's composition would materially affect the basic and novel characteristics of the claimed invention.

Claims 1-3, 15, 16, 17, 21 and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Nut-Med (www.caribbean-connexion.com/exports/nut-med.htm) (8/2003).

Nut-Med disclosed a pain relieving spray which comprised nutmeg oil and menthol. Again, it is determined that claim 22, which states "method for treating....administering....a pain relieving formulation comprising nutmeg oil and added menthol in an amount effective to relieve pain, without administering other analgesics is anticipated by Morri I. for the following reason: Although the claim states 'an amount effective to relive pain, without administering other topical analgesics' does not mean that other analgesics are not present in the composition. This statement simply means that if there were no other analgesics present, that the nutmeg oil and menthol would relieve pain alone, which is rendered an inherent property of the composition.

It is noted that the addition of a container, as well as labeling instructions does not materially change the composition of claim 1, although the Nut-med composition clearly was sold in a bottle and did come with labeling instructions as can be seen on the WWW print-out.

Where claim 21 states that the nutmeg oil and menthol are effective to relieve pain without additional non-menthol analgesics, is also non-limiting because it does not change the composition, but rather states a characteristic of the composition.

Nutmeg oil is prepared from steam distillation of *Myristica fragrans* as indicated by IPCSPIM (see p. 8 of 23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-19, 21-22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morri I. (JP 362059219 A) in view of IPCSPIM (1997).

The teachings of Morri, I. were discussed *supra*. Morri, I, did not specifically state wherein the nutmeg oil was non-irritating, wherein the formulation comprised specific amounts of nutmeg oil and menthol as recited in claims 6, 7, 9-11, 14, 18, 19 or 24.

Also indicated by IPCSPIM, there are mainly two types of nutmeg oil, East Indian and West Indian nutmeg oil (p. 8 of 23). IPCSPIM also teaches that myristicin and safrole are toxic compounds indigenous to nutmeg, and that myristicin accounts for 3.86 to 12.7% of nutmeg oil and safrole accounts for 0.53 to 3.42% of nutmeg oil (p.9 of 23).

One of ordinary skill in the art would have been motivated to substitute the nutmeg oil as disclosed by Morri, I. with a nutmeg oil which comprised non-irritating

nutmeg oil (i.e., low myristicin and safrole concentrations) in order to limit the toxicology of the composition.

Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an *art-recognized result-effective variable* which would have been routinely determined and optimized in the pharmaceutical art. Variations of components in nutritional compositions were well known in the art. One of ordinary skill in the art would have been motivated to modify the proportions of active ingredients in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals who needed treatment. Such variations in amounts of pharmaceutically active ingredients is considered merely optimization of result effective variables, conventional practice in the art of pharmacology.

It is noted that claim 14 which states 'consists essentially of nutmeg oil and added menthol, the added menthol being about 2% by weight' is considered as obvious

over the references. As it was stated supra under the rejection under 35 USC 102(b), there is no indication that the additional ingredients disclosed by Morri would materially affect the basic and novel characteristics of the claimed invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 5 and 20 are free of the art. The closest prior art of record is Morri I. (JP 362059219 A) (discussed supra). Morri disclosed the use of menthol and nutmeg oil in a formulation admixed with other ingredients such as eucalyptus oil and turpentine oil. Morri did not provide any motivation to include pimento berry oil to the composition, nor to use a nutmeg oil with the particular ingredient of claim 5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

11/23/04